

**§515.22**

**21 CFR Ch. I (4-1-02 Edition)**

(2) The methods used in and the facilities and controls used for the manufacturing, processing, and packaging of such animal feed are not adequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

(3) The facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published under section 512(i) of the act.

(b) The Commissioner, as provided in §515.30, shall expeditiously notify the applicant of an opportunity for a hearing on the question of whether such application is approvable, unless by the 30th day following the date of issuance of the letter informing the applicant of the intention to issue a notice of opportunity for a hearing the applicant:

- (1) Withdraws the application; or
- (2) Waives the opportunity for a hearing; or
- (3) Agrees with the Commissioner on an additional period to precede issuance of such notice of hearing.

**§515.22 Suspension and/or revocation of approval of a medicated feed mill license.**

(a) The Secretary of Health and Human Services may suspend a medicated feed mill license approved under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) and give the person holding the medicated feed mill license application prompt notice of this action and afford the applicant the opportunity for an expedited hearing on a finding that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended.

(b) The Commissioner of Food and Drugs (the Commissioner) shall notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

- (1) That the application contains any untrue statement of a material fact; or

(2) That the applicant has made any changes that would cause the application to contain any untrue statements of material fact or that would affect the safety or effectiveness of the animal feeds manufactured at the facility unless the applicant has supplemented the application by filing a supplemental application under §515.11.

(c) The Commissioner may notify in writing the person holding an application approved under section 512(m)(2) of the act and afford an opportunity for a hearing on a proposal to revoke approval of such application if the Commissioner finds:

- (1) That the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under sections 512(m)(5)(A) or 504(a)(3)(A) of the act, or the applicant has refused to permit access to, or copying, or verification of, such records as required by sections 512(m)(5)(B) or 504(a)(3)(B) of the act; or

(2) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the methods used in, or the facilities and controls used for, the manufacture, processing, packing, and holding of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(3) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the labeling of any animal feeds, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of; or

(4) That on the basis of new information before him, evaluated together with the evidence before him when such license was issued, the facility has manufactured, processed, packed, or

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held animal feed bearing or containing a new animal drug adulterated under section 501(a)(6) of the act, and the facility did not discontinue the manufacture, processing, packing, or holding of such animal feed within a reasonable time after receipt of written notice from the Commissioner specifying the matter complained of.

### **§ 515.23 Voluntary revocation of medicated feed mill license.**

A license issued under section 512(m)(2) of the Federal Food, Drug, and Cosmetic Act (the act) will be revoked on the basis of a request for its revocation submitted in writing by a responsible individual holding such license on the grounds that the facility no longer manufactures any animal feed covered under § 558.4(b) of this chapter. A written request for such revocation shall be construed as a waiver of the opportunity for a hearing as otherwise provided for in this section. Revocation of approval of a medicated feed mill license under the provisions of this paragraph shall be without prejudice.

### **§ 515.24 Notice of revocation of a medicated feed mill license.**

When a license approved under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) is revoked by the Commissioner of Food and Drugs (the Commissioner), the Commissioner will give appropriate public notice of such action by publication in the FEDERAL REGISTER.

### **§ 515.25 Revocation of order refusing to approve a medicated feed mill license application or suspending or revoking a license.**

The Commissioner of Food and Drugs (the Commissioner), upon his/her own initiative or upon request of an applicant stating reasonable grounds therefor and if the Commissioner finds that the facts so require, may issue an order approving a medicated feed mill license application that previously has had its approval refused, suspended, or revoked.

### **§ 515.26 Services of notices and orders.**

All notices and orders under this part 515 and section 512 of the Federal Food,

Drug, and Cosmetic Act (the act) pertaining to medicated feed mill licenses shall be served:

(a) In person by any officer or employee of the Department of Health and Human Services designated by the Commissioner of Food and Drugs; or

(b) By mailing the order by certified mail addressed to the applicant or respondent at the applicant or respondent's last known address in the records of the Food and Drug Administration.

## **Subpart C—Hearing Procedures**

### **§ 515.30 Contents of notice of opportunity for a hearing.**

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the FEDERAL REGISTER and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis